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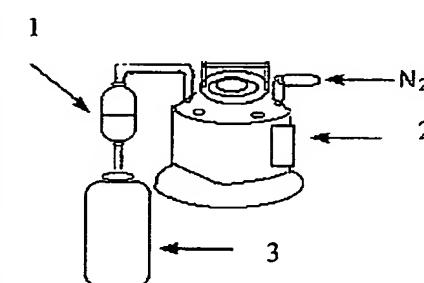
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(54) Title: PROCESS FOR THE PREPARATION OF ANHYDROUS AND HYDRATED ACTIVE PHARMACEUTICAL INGREDIENTS (APIs); STABLE PHARMACEUTICAL COMPOSITIONS PREPARED FROM THE SAME AND USES OF SAID COMPOSITIONS



(57) Abstract: This invention describes a process for the production of ANHYDROUS active pharmaceutical ingredients (APIs); a process for the preparation of HYDRATED active pharmaceutical ingredients, a process for the preparation of sterile and stable injectable solutions, and their use, more specifically, APIs which are taxane derivatives, especially (2R,3S) 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7- β -10- β -tri-hydroxy-9-oxo-tax-11-en-13 α -il 3-tert-butoxycarbonylamo-2-hydroxy-3-phenylpropionate (I); 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7 β -10- β -tri-hydroxy-9-oxo-tax-11-en-13 α -il (2R,3S) 3-benzoylamo-2-hydroxy-3-phenylpropionate (II), and particularly 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7 β -10- β -tri-hydroxy-9-oxo-tax-11-en-13 α -il (2R,3S) 3-tert-butoxycarbonylamo-2-hydroxy-3-phenylpropionate tri-hydrate (III).

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